4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-3403]

Clarifying Current Roles and Responsibilities Described in the Coordinated Framework for the Regulation of Biotechnology and Developing a Long-Term Strategy for the Regulation of the Products of Biotechnology; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: Under the auspices of the National Science and Technology Council, the Food and Drug Administration (FDA or the Agency), along with the Office of Science and Technology Policy (OSTP), the Environmental Protection Agency (EPA), and the United States Department of Agriculture (USDA), is announcing a public meeting, to be held on October 30, 2015, to discuss the memorandum entitled, "Modernizing the Regulatory System for Biotechnology Products," issued by the Executive Office of the President (EOP) in July 2015. The purpose of the meeting is to inform the public about the activities described in the July 2015 memorandum; invite oral comments from interested parties; and provide information about how to submit written comments, data, or other information to the docket.

DATES: See section II, "How to Participate in the Public Meeting" in the SUPPLEMENTARY INFORMATION section of this document for the date and time of the public meeting, closing dates for advance registration, and information on deadlines for submitting either electronic or

written comments to FDA's Division of Dockets Management. Comments may be submitted in writing until November 13, 2015.

ADDRESSES: See section II, "How to Participate in the Public Meeting" in the SUPPLEMENTARY INFORMATION section of this document.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on http://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2015-N-3403 for "Clarifying Current Roles and Responsibilities Described in the Coordinated Framework for the Regulation of Biotechnology and Developing a Long-Term Strategy for the Regulation of the Products of Biotechnology; Public Meeting." Comments received will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION". The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on http://www.regulations.gov. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be

made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

For general questions about the meeting, to request an opportunity to make an oral presentation at the public meeting, to submit the full text or summary of an oral presentation, or for special accommodations due to a disability, contact the Office of Policy, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-4830, email: BiotechnologyUpdate@fda.hhs.gov.

For questions about the memorandum entitled, "Modernizing the Regulatory System for Biotechnology Products," or related activities described in that memorandum, contact the National Science and Technology Council: Emerging Technologies Interagency Policy Coordination Committee, Office of Science and Technology Policy, Executive Office of the President, Eisenhower Executive Office Building, 1650 Pennsylvania Ave., Washington DC

20504, 202-456-4444, online: https://www.whitehouse.gov/webform/contact-emerging-technologies-interagency-policy-coordinating-committee-national-science-and.

SUPPLEMENTARY INFORMATION:

I. Background

In 1986, OSTP issued the Coordinated Framework for Regulation of Biotechnology (CF), which outlined a comprehensive Federal regulatory policy for ensuring the safety of biotechnology products. The CF sought to achieve a balance between regulation adequate to ensure the protection of health and the environment while maintaining sufficient regulatory flexibility to avoid impeding innovation (51 FR 23302; June 26, 1986) (Ref. 1).

In 1992, OSTP issued an update to the CF that set forth a risk-based, scientifically sound basis for the oversight of activities that introduce biotechnology products into the environment (57 FR 6753; February 27, 1992) (Ref. 2). The update affirmed that Federal oversight should focus on the characteristics of the product, the environment into which it is being introduced, and the intended use of the product, rather than the process by which the product is created.

On July 2, 2015, the EOP issued a memorandum entitled, "Modernizing the Regulatory System for Biotechnology Products," (the EOP memorandum) directing the primary federal Agencies that have oversight responsibilities for the products of biotechnology--EPA, FDA, and USDA--to update the CF to clarify current roles and responsibilities of the Agencies that regulate the products of biotechnology, develop a long-term strategy to ensure that the Federal biotechnology regulatory system is prepared for the future products of biotechnology, and commission an independent, expert analysis of the future landscape of biotechnology products (Ref. 3). These efforts will build on the regulatory principles described in the CF and the 1992 update to the CF. The EOP memorandum's objectives are to ensure public confidence in the

regulatory system and to prevent unnecessary barriers to future innovation and competitiveness by improving the transparency, coordination, predictability, and efficiency of the regulation of biotechnology products while continuing to protect health and the environment.

The July 2, 2015, EOP memorandum stated that the update to the CF should clarify the current roles and responsibilities of the Agencies that regulate the products of biotechnology by accomplishing the following four objectives:

1. Clarifying which biotechnology product areas are within the authority and responsibility of each Agency.

2. Clarifying the roles that each Agency plays for different product areas, particularly for those product areas that fall within the responsibility of multiple agencies, and how those roles relate to each other in the course of a regulatory assessment.

3. Clarifying a standard mechanism for communication and, as appropriate, coordination among Agencies, while they perform their respective regulatory functions, and for identifying Agency designees responsible for this coordination function.

4. Clarifying the mechanism and timeline for regularly reviewing, and updating as appropriate, the CF to minimize delays, support innovation, protect health and the environment, and promote the public trust in the regulatory systems for biotechnology products.

As noted in the EOP memorandum, "biotechnology products" refers to products developed through genetic engineering or the targeted or in vitro manipulation of genetic information of organisms, including plants, animals, and microbes. It also covers some of the products produced by such plants, animals, and microbes or their derived products as determined by existing statutes and regulations. Products such as human drugs and medical devices are not the focus of the activities described in the EOP memorandum.

In addition, on October 6, 2015, OSTP issued a notice of request for information (RFI) to solicit data and information, including case studies, that can inform the development of the proposed update to the CF and the development of a long-term strategy consistent with the objectives described in the July 2, 2015, EOP memorandum (80 FR 60414). In addition to the RFI, the EOP noted that it will hold three public engagement sessions over the next 12 months (Ref. 4), and that the current update to the CF will undergo public notice and comment before it is finalized. This notice is announcing the first public engagement session.

The purpose of this first public meeting is to inform the public about the activities described in the EOP memorandum; invite oral, stakeholder comments relevant to those activities; and provide information about how to submit written comments, data, or other information to the docket. At this public meeting, OSTP will provide an overview of the CF and the 1992 update to the CF, and discuss the activities described in the EOP memorandum. EPA, FDA, and USDA will provide an overview of their current approaches to regulating products of biotechnology. The agenda for this public meeting will be posted approximately 5 days before the meeting at:

http://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm463783.htm.

II. How to Participate in the Public Meeting

OSTP, EPA, FDA, and USDA (collectively referred to as "we" or "us") are holding the public meeting under the auspices of the National Science and Technology Council. The meeting will be held on October 30, 2015, in the White Oak Great Room, at FDA's White Oak Campus, Building 31 Conference Center, the Great Room (rm. 1503 B&C), 10903 New Hampshire Ave., Silver Spring, MD 20993-002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be

performed. For parking and security information, please refer to http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm. Due to limited space and time, we encourage all persons who wish to attend the meeting to register early and in advance of the meeting. There is no fee to register for the public meeting, and registration will be on a first-come, first-served basis. Onsite registration will be accepted, as space permits, after all preregistered attendees are seated.

Those requesting an opportunity to make an oral presentation during the time allotted for public comment at the meeting are asked to submit a request in advance and to provide information about any specific topic or issue to be addressed. There will not be an opportunity to display materials such as slide shows, videos, or other media during the meeting. If time permits, individuals or organizations that did not register in advance may be granted the opportunity to make an oral presentation. We would like to maximize the number of individuals who make a presentation at the meeting and will do our best to accommodate all persons who wish to make a presentation or express their opinions at the meeting.

We encourage persons and groups who have similar interests to consolidate their information for presentation by a single representative. After reviewing the presentation requests, we will notify each participant before the meeting of the approximate start time of their presentation and of the amount of time allotted for the comment.

While oral presentations from specific individuals and organizations will be necessarily limited due to time constraints during the public meeting, interested parties may submit electronic or written comments to the docket. All relevant data and documentation should be submitted with the comments to Docket No. FDA-2015-N-3403.

Table 1 provides information on participation in the public meeting.

Table 1.--Information on Participation in the Public Meeting and on Submitting Comments to the Docket

	Date	Electronic Address	Address	Other Information
Public meeting	October 30, 2015	http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm	FDA's White Oak Campus, Building 31 Conference Center, the Great Room (1503-B&C), 10903 New Hampshire Ave., Silver Spring, MD 20993-002.	
Deadline for registration	October 21, 2015	http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm Docket No. FDA-2015-N-3403	We encourage you to use electronic registration if possible.[1]	There is no registration fee for the public meetings. Early registration is recommended because seating is limited.
Request to make a public comment	October 21, 2015	http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm		Requests made on the day of the meeting to make an oral presentation will be granted as time permits. Information on requests to make an oral presentation may be posted without change to http://www.regulations.gov, including any personal information provided.
Request special accommodations due to a disability	October 21, 2015	Email: BiotechnologyUpdate@fda.hhs.gov	Office of Policy, Office of the Commissioner, U.S. Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-4830.	
Closing date for written comments	November 13, 2015	http://www.regulations.gov	See ADDRESSES above.	

[1] For questions about registering for the meeting, to register by phone, or to submit a notice of participation by mail, FAX or email, contact: Office of Policy, Office of the Commissioner, U.S. Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-4830, email: BiotechnologyUpdate@fda.hhs.gov.

III. Comments, Transcripts, and Recorded Video

Information and data submitted voluntarily to us will become part of the administrative record for this activity, and will be accessible to the public at http://www.regulations.gov. The transcript of the proceedings from the public meeting will become part of the administrative record for this activity. Please be advised that as soon as a transcript is available, it will be accessible at http://www.regulations.gov and on FDA's Web site at: http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm. It may also be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information, 5630 Fishers Lane, rm. 1035, Rockville, MD 20857. Additionally, we will live webcast and record the public meeting. Once the recorded video is available, it will be accessible on FDA's Web site at: http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm.

IV. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at http://www.regulations.gov. FDA has verified the Web site addresses as of the date this document publishes in the Federal Register, but Web sites are subject to change over time.

1. Executive Office of the President. Office of Science and Technology Policy. Coordinated Framework for Regulation of Biotechnology. 51 FR 23302, June 26, 1986.

Available online at:

http://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf.

2. Executive Office of the President. Office of Science and Technology Policy. Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products Into the Environment. 57 FR 6753, February 27, 1992. Available online at:

https://www.whitehouse.gov/sites/default/files/microsites/ostp/57_fed_reg_6753__1992.pdf.

3. Executive Office of the President. Office of Science and Technology Policy, Office of Management and Budget, United States Trade Representative, and Council on Environmental Quality. Modernizing the Regulatory System for Biotechnology Products, July 2, 2015. Available online at:

https://www.whitehouse.gov/sites/default/files/microsites/ostp/modernizing_the_reg_system_for_biotech_products_memo_final.pdf.

4. Executive Office of the President. Improving Transparency and Ensuring Continued Safety in Biotechnology, blog post, July 2, 2015. Available online at:

https://www.whitehouse.gov/blog/2015/07/02/improving-transparency-and-ensuring-continued-safety-biotechnology.

Dated: October 9, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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